

# EXHIBIT C

1 SUPERIOR COURT OF THE STATE OF CALIFORNIA  
FOR THE COUNTY OF KERN  
2 CASE NO. S-1500-CV 279123 LHB

COLEEN M. PERRY, PLAINTIFF

5 vs.

HUNG T. LUU, M.D.,  
7 JOHNSON & JOHNSON, a New Jersey  
Corporation; ETHICON, INC., a  
8 New Jersey Corporation; and  
DOES 1-60,

13           The deposition of SCOTT A. GUELCHEER, Ph.D.,  
14   called by the Defendants for examination, taken  
15   before Michelle E. Kerr, RPR, a Notary Public in and  
16   for the Commonwealth of Kentucky, Daviess County, at  
17   1719 West End Avenue, Nashville, Tennessee, on  
18   December 18, 2014, commencing at 9:40 a.m.

1           A    Yes.  It's been registered with the secretary  
2                   of state.

3           Q    As I understand it from your testimony at  
4                   Huskey and other matters, you believe your  
5                   expertise is in the field of biomaterials  
6                   design?

7           A    That's one way of saying it.  I have  
8                   expertise in biomaterials science and  
9                   engineering.  Another way you could say it is  
10                  that my work involves design of materials for  
11                  use as bone grafts or skin grafts, design of  
12                  biomaterials as diagnostics for studying  
13                  cancer metastasis.

14          Q    You have a Ph.D., correct?

15          A    Yes.

16          Q    Any higher education than that?

17          A    I did a postdoctoral research training at  
18                  Carnegie Mellon in biomedical engineering.

19          Q    But that was not something for which a degree  
20                  was earned; is that correct?

21          A    It's not a degree, but it's postdoctoral  
22                  training.  It counts as training.

23          Q    You're not a medical doctor, correct?

24          A    No, I'm not a medical doctor.

25          Q    You're not a pathologist?

1 A I'm not a pathologist.

2 Q You don't treat any patients, correct?

3 A I don't treat patients.

4 Q You're not a toxicologist, correct?

5 A I'm not a toxicologist.

6 Q What is the difference between your expertise  
7 and Dr. Dunn's expertise?

8 A So Dr. Dunn and I have overlapping expertise  
9 in polymer science and engineering. My  
10 expertise is differentiated from Dr. Dunn's  
11 in biomaterials, preclinical testing of  
12 biomaterials, evaluation of biomaterials  
13 using in vitro and in vivo models. Those  
14 would be some examples of how my expertise is  
15 differentiated from Dr. Dunn's.

16 Q Is Dr. Dunn more of a polymer chemist than  
17 you are?

18 A I would not state it this way. I've had  
19 extensive experience in polymer chemistry,  
20 science and engineering. I've worked for  
21 several companies in the area of polymers.  
22 My postdoctoral training was in polymers for  
23 bone scaffolds. And for the past ten years  
24 at Vanderbilt, I've been working on polymers  
25 and I taught -- and I developed and taught a



1 solution of 20 percent hydrogen peroxide with  
2 cobalt chloride, and I don't remember the  
3 exact amount. That's the solution.

4 Q And this solution is used for the in vitro  
5 testing of mesh?

6 A This solution was first developed by Dr. Jim  
7 Anderson in 1993. It was first published --  
8 his group published a number of papers on it.  
9 I published two papers with it. It's used to  
10 assess the degradation of biomaterials under  
11 oxidative conditions that are similar to  
12 those in the human body, more specifically,  
13 that are similar to those under conditions  
14 where there are adherent inflammatory cells  
15 in the biomaterial, the foreign body  
16 reaction, I should say, the effects of the  
17 foreign body reaction on the stability of the  
18 biomaterial.

19 It's a very general well-known  
20 established test that's been cited dozens of  
21 times.

22 Q So did Ms. Talley or any of your other  
23 graduate students do any in vitro testing on  
24 the mesh?

25 A No. As I said before, that testing was done

1           Q    My question is this.  It's straight forward.  
2                The fact that you see chemical oxidation,  
3                that does not mean that you would also see  
4                under SEM analysis physical degradation if  
5                you were to look at that particular time; is  
6                that correct?

7                               MR. KUNTZ:  Objection.  Asked  
8                and answered.  Calls for speculation, and is  
9                an incomplete hypothetical.  But go ahead.

10          A    This is a speculative question.  What I'm  
11                saying is, if there is oxidative changes, the  
12                body of literature teaches within a  
13                reasonable degree of scientific certainty  
14                that there will be at some time physical  
15                degradation.  That's what the literature is  
16                teaching us.

17   BY MR. SNELL:

18          Q    You keep saying at some time there will be  
19                physical degradation.  At what time will  
20                there be physical degradation?

21          A    As I've said in my previous testimony, it's  
22                unpredictable.  And that's a problem for the  
23                design of the device, because it's subject to  
24                changes that can happen that you can't  
25                predict the timing of these changes and what

1 the implications will be.

2 Q Do you have an opinion as to what is the  
3 earliest point in time where there can be  
4 physical degradation of Ethicon's Prolene  
5 polypropylene used in TVT Abbrevio?

6 A Again, that's a speculative question. I  
7 believe that upon implantation, the device  
8 will be colonized by adherent inflammatory  
9 cells. This is well-known in the literature,  
10 the foreign body reaction. Those cells will  
11 secrete species that oxidize it. The timing  
12 of all these events can depend on a number of  
13 factors, the nature of the inflammatory  
14 response where it's implanted, the mechanical  
15 stresses in the environment, whether there is  
16 a bacterial infection.

17 The timing can be highly variable. It  
18 can happen early or it can happen late. The  
19 point is that it's unpredictable. That's  
20 what I've been saying.

21 Q Well, I would like to know what does the  
22 literature teach you about the earliest point  
23 in time when you can say there is physical  
24 degradation of the Prolene polypropylene  
25 mesh?

1 I don't want to rehash everything you  
2 talked about in Huskey. I know you talked  
3 about what was seen in two years and I  
4 believe five or seven years in a dog study  
5 and things like that. So with all of those  
6 principles that you've already testified  
7 about, let me just back up and re-ask it.

8 A Okay.

9 MR. KUNTZ: Objection.

10 BY MR. SNELL:

11 Q What is the earliest point in time that you  
12 can say that there is physical degradation of  
13 the Prolene polypropylene mesh?

14 A I just can't answer that question. There are  
15 too many factors that can influence it. To  
16 say -- again, it's too speculative. It  
17 depends on many factors in addition to the  
18 chemical oxidation.

19 Q Based on all of the literature that you saw,  
20 what was the earliest time reported that  
21 there was physical degradation of the Prolene  
22 polypropylene mesh?

23 A For Prolene polypropylene, I can say from the  
24 Clave paper and the explants that were  
25 studied in Clave, he recorded degradation in



1 Abbrevio?

2 A I have not.

3 Q Have you done any testing of any type on TVT  
4 product for stress incontinence? And when I  
5 stay TVT, I mean Ethicon's particular TVT  
6 product.

7 A So only the testing performed at Dr. Dunn's  
8 laboratory. Just to be clear, Dr. Dunn did  
9 that testing. I consulted and advised. We  
10 discussed it, agreed to do it, but Dr. Dunn  
11 physically performed the testing.

12 Q Tell me what testing did Dr. Dunn do on an  
13 Ethicon TVT device. As I had read -- and  
14 I'll tell you why I'm asking. As I had read  
15 your Huskey deposition testimony, he had done  
16 some testing on maybe one or more AMS meshes  
17 and Boston Scientific meshes.

18 A These are new testing that we've done.

19 Q Let me just back up then. So as I understand  
20 it, Dr. Dunn has done some testing on Ethicon  
21 TVT products?

22 A Yes.

23 Q Are you relying on that testing for your  
24 opinions in the Perry case?

25 A Let me look at my opinions for a minute.

1 Yes, I am relying on that testing. So I  
2 should say, I formed my opinions based on the  
3 literature review. My opinions are the same  
4 as they were in the Huskey case on this  
5 particular topic of oxidation and  
6 degradation, and this testing further  
7 confirms my opinions.

8 And the testing was specifically done to  
9 answer the question that Ethicon raised  
10 during the trial in August, that Prolene is  
11 different from polypropylene and doesn't  
12 oxidize because it has antioxidants.

13 So in the testing done by Dr. Dunn, the  
14 goal was to answer the question can Prolene  
15 in a TVT device oxidize and degrade. And we  
16 saw oxidation and degradation of the surface  
17 pitting in that testing, in the oxidative  
18 medium that I was describing earlier. So the  
19 testing was performed to answer a very  
20 specific question of -- and to answer the  
21 specific question of can the Prolene  
22 polypropylene oxidize. That was the purpose  
23 of the test.

24 Q Where is this testing, all of the notebooks,  
25 the results, the data generated from it that

1           you are relying on?

2           A    So this is on the disk that was provided.

3           Q    Okay. Show me where on the disk that that is  
4                this TVTG testing is located.

5           A    I don't have a computer but --

6           Q    Can you use Mr. Kuntz'?

7                         MR. KUNTZ: He can.

8                         Let's go off the record for a second.

9                         (Off-the-record discussion.)

10       BY MR. SNELL:

11           Q    Counsel is looking at the thumb drive.

12                Obviously, I can't look at it and question  
13                the witness about 6,000 files today. Let me  
14                just get some basic information about this  
15                testing.

16                The testing that was performed on  
17                Ethicon's TVT mesh, what specific device or  
18                devices were the subject of the testing?

19           A    I believe it was the TVT.

20           Q    The original TVT retropubic?

21           A    I believe so. And we also tested an  
22                unstabilized polypropylene controlled, it had  
23                no antioxidant.

24           Q    Okay. You said it was an unstabilized  
25                Prolene polypropylene?



1           A    No.  It's polypropylene without antioxidants.  
2                So it would be the equivalent of -- in the  
3                Liebert paper where they tested the  
4                monofilament with no stabilizers.  It's a  
5                polypropylene that has no antioxidants.  So  
6                it's unstabilized polypropylene I would call  
7                it.

8           Q    So you didn't test the TVT retropubic mesh  
9                with antioxidants to the TVT retropubic mesh  
10               with antioxidants?

11          A    No, we can't get TVT without the -- the TVT  
12                is made from Prolene that has that Prolene  
13                antioxidant package, because that's what we  
14                tested, that's what we could get.  So we had  
15                that exemplar, Dr. Dunn had it, and we  
16                compared that to the unstabilized  
17                polypropylene.  We also tested two Boston  
18                Scientific meshes, but that's not in the  
19                materials that we presented.  That's  
20                different.

21          Q    You are not relying on this Boston Scientific  
22                testing for your opinions in this matter,  
23                correct?

24          A    I am not.

25          Q    Okay.

1 A I am just disclosing what we did.

2 Q This TVT retropubic device that Dr. Dunn  
3 tested, was it one single device or was it a  
4 batch or numerous ones?

5 A I believe it was one device with three  
6 replicate pieces, three distinct pieces cut  
7 from -- it was three or four. I can't  
8 remember the details. I would have to look  
9 at it. But there were multiple replicates  
10 cut from the same mesh.

11 Q And the unstabilized polypropylene control,  
12 where was that obtained from?

13 A I would have to look at the document to look  
14 at the documents for the exact source, but it  
15 was purchased from a third-party vendor that  
16 sells polypropylene with antioxidants,  
17 unstabilized polypropylene.

18 Q Do you know the vendor?

19 A I can't remember. It's in the documents. I  
20 would have to find it.

21 Q Do you know who purchased this control?

22 A Dr. Dunn purchased it and did all of this  
23 work.

24 Q You personally were not the one who did any  
25 of this testing on the TVT retropubic device,

1 correct?

2 A No. As I said previously, Dr. Dunn and I  
3 consulted, and Dr. Dunn did all of the work  
4 physically through his company.

5 Q So am I correct that you did not do any of  
6 the physical testing of this TVT or the  
7 control?

8 A That's right. Dr. Dunn did.

9 Q And that was done at his company?

10 A Yes.

11 Q Was that testing done out of his house?

12 A I don't know. Maybe some of it was done from  
13 his house. I don't remember.

14 Q Do you know where the testing took place on  
15 this TVT retropubic compared to the  
16 polypropylene control?

17 A It was done in his lab at Vanderbilt.

18 Q Who paid for the testing that Dr. Dunn  
19 performed comparing the TVT retropubic to the  
20 unstabilized polypropylene control?

21 A I should clarify that all of these responses  
22 I'm telling you to the best of my knowledge.  
23 And if Dr. Dunn contradicts what I'm saying,  
24 it's because I didn't remember it correctly.  
25 I believe that this testing was billed to the

1           litigation, but Dr. Dunn would have to  
2           confirm that.

3           Q   Is your basis for your testimony in that  
4           regard something that Dr. Dunn told you?

5           A   Yes, I'm basing it on -- I have not seen  
6           those invoices. That would be between  
7           Dr. Dunn and plaintiff's counsel.

8           Q   Did Dr. Dunn physically do all of his  
9           testing?

10          A   Again, I believe that he did, but I don't  
11          know the details of -- he would be the one  
12          that would have to speak to that.

13          Q   Unfortunately, he is not identified as an  
14          expert here.

15          A   I understand that.

16          Q   Were you present for any of the physical  
17          testing of the TVT retropubic or the  
18          unstabilized polypropylene control?

19          A   Was I present?

20          Q   Present meaning on the premises where the  
21          testing was performed, such that you could  
22          yourself observe the testing.

23          A   Well, the testing was just very simple.  
24          Dr. Dunn placed the -- I'm trying to answer  
25          your question as best I can. So Dr. Dunn

1 placed the specimens in vials. They were  
2 weighted down with glass beads in this  
3 oxidative medium that I was describing that  
4 simulates the environment between the  
5 adherent inflammatory cells and the  
6 biomaterial. I have seen those vials.

7 And then at different time points,  
8 Dr. Dunn removed the test specimens, rinsed  
9 and dried them, and measured RI spectra. And  
10 I've seen those dried specimens. I've seen  
11 the specimens, and so I have seen aspects of  
12 the testing, but I didn't watch him do the  
13 testing. But the testing essentially  
14 involves incubating the material in a  
15 solution, and then taking it out and testing  
16 it by FTIR and SEM.

17 Q When was this testing on the TVT retropubic  
18 device done?

19 A September and October of 2014.

20 Q And it was on a single TVT retropubic  
21 exemplar, meaning that mesh had not been in  
22 the body at all?

23 A That's correct.

24 Q When did you first discuss with Dr. Dunn this  
25 testing on the TVT retropubic exemplar?



1           A    Same time frame.  Maybe August -- it would  
2                   have been September of 2014 after the Huskey  
3                   trial.  And, again, the motivation for the  
4                   tests was based on Ethicon's statements  
5                   during trial that we had not tested it and  
6                   couldn't -- we could not say definitively  
7                   that Prolene polypropylene oxidizes, and that  
8                   was the motivation for the test.

9                   So this is what was said in Huskey trial,  
10                  we decided to do the test to answer that  
11                  specific question, can Prolene polypropylene  
12                  oxidize.

13          Q    Now, Dr. Dunn's Vanderbilt lab, is that on  
14                  the premises here at Vanderbilt?

15          A    Yes, his lab is at Vanderbilt.

16          Q    Do you know if any graduate students or  
17                  other people were involved in the testing?

18          A    Dr. Dunn has employees.  I know that.  To  
19                  what extent they were involved in the  
20                  testing, I can't speak to.  Again, Dr. Dunn  
21                  just did all of his.  I don't know those  
22                  details.

23                  I should qualify my comment.  Dr. Dunn  
24                  does not have employees, but I know that he  
25                  does pay contractors for services like he

1           A    But the questions are being phrased that  
2                    you're trying to misrepresent my testimony  
3                    and misrepresent what I'm saying.

4           Q    I'm not trying to misrepresent your  
5                    testimony.

6           A    You are.

7           Q    I'm asking you a factual question.

8           A    And the question is --

9           Q    Was there a horse in the room at the time of  
10                  the test, yes or no?  No.

11                  Was there a macrophage in the test, yes  
12                  or no?

13                  The interpretation, I will get to that,  
14                  but I have simple questions, sir, and I'm  
15                  entitled to simple answers if they're simple  
16                  questions.  You can talk to Mr. Kuntz all  
17                  night long about your interpretation.  That's  
18                  fine.  But I'm actually going to ask you  
19                  about your interpretation too.

20          A    And I'm entitled to answer questions as I  
21                  need to.  And I'm not going to be put into  
22                  this difficult position of having things  
23                  recorded as my testimony that's not what I've  
24                  ever been saying.

25          Q    You would agree that -- let me back up.  What



1 is it that you believe this test on this  
2 single TVT device compared to the control  
3 shows?

4 A I believe that it shows Prolene polypropylene  
5 used to manufacture the TVT device can  
6 oxidize and degrade under oxidative  
7 conditions similar to those experienced in  
8 the human body after implantation.

9 Q What documents or files out of those 6,000  
10 plus show the oxidation?

11 A The oxidation is evidenced by FTIRs spectra  
12 that were measured in weeks zero, one, two,  
13 three, four and five. In the FTIRs spectra,  
14 we saw minimal hydroxyl and carbonyl peaks  
15 until week five, where we saw a significant  
16 increase in the magnitude of the hydroxyl  
17 and/or carbonyl peaks, which was indicative  
18 of a chemical induction.

19 Q So what are the file names and the documents  
20 that showed this out of the 6,000?

21 A I don't remember the file names.

22 Q Well, I'm entitled to know them.

23 A I know. And I have to look at it. I don't  
24 have it here with me. I know that you're  
25 entitled to have it, but I don't have it here

1 Dr. Iakovlev's, but I don't know.

2 Q And you understand that doctors are the ones  
3 who actually do differential diagnoses and  
4 draw conclusions about what complications  
5 patients have?

6 A Could you explain differential diagnosis,  
7 please?

8 Q Let me ask you, do you know what a  
9 differential diagnosis is?

10 A Not precisely, I don't think. So I suppose I  
11 wouldn't do that. I mean, it sounds like a  
12 medical term to me.

13 Q Opinion number nine, explain that opinion to  
14 me. Clearly, this is different.

15 A So after reviewing all of the Ethicon  
16 documents and some published papers, my  
17 conclusion was that this TVT Abbrevio mesh is  
18 stiffer. There are several e-mails from  
19 inventors of the mesh, such as Dr. Della  
20 Valle, Dr. Nelson, that observed this  
21 increase in stiffness, complained about an  
22 increase in complications, asserted that this  
23 mesh was different, and you could not rely  
24 upon TVT machine-cut mesh data to support the  
25 notion that TVT Abbrevio is the same.

1 do those calculations now, and I review them.  
2 There are software programs that you can use  
3 to do this. It's pretty routine, I think.

4 Q The software plugs in the number of tests and  
5 the time points and it generates --

6 A We can do this with software, yeah.

7 Q You haven't published or presented on this  
8 test, correct, that was done with the TVT  
9 device and the pellet control?

10 A We presented it at the AIChE annual meeting.  
11 And I think those slides are on the reliance  
12 list.

13 Q For the TVT?

14 A In that presentation, we did not identify the  
15 source of the mesh.

16 MR. KUNTZ: I don't think that's  
17 on there, Burt. We will get it to you,  
18 though.

19 A We called it mesh 1, 2 and 3. We did not  
20 identify it as TVT.

21 BY MR. SNELL:

22 Q Do you know if it was TVT or would you have  
23 to go back and look?

24 A Yes, it was TVT. We chose not to disclose  
25 that at that meeting.

1 Q Where was this at?

2 A The AIChE, it's the American Institute of  
3 Chemical Engineers. If you would like, I can  
4 circle it on my CV. Would that help you?

5 Q Sure. That's fine. Or if you just want to  
6 look at your CV and tell me what page or  
7 number.

8 A That's fine too. On the CV, it's  
9 presentation number 154.

10 Q Was that a presentation that you actually  
11 gave and presented or did someone else do it?

12 A Dr. Dunn and I both gave the presentation.

13 Q Was it presented orally?

14 A It was.

15 Q Okay. So I would like to request a copy of  
16 that.

17 Did you have to prepare a manuscript in  
18 connection with that?

19 A No. We submitted a short abstract, which is  
20 available online. We elected not to submit  
21 an extended abstract.

22 Q What was the reason why you didn't submit an  
23 extended abstract?

24 A We typically don't do that for that meeting.

25 Q Is that the only presentation you have made

1 Q And just so I'm clear, you didn't conduct any  
2 type of differential diagnosis to assess the  
3 cause of dyspareunia or pain or the potential  
4 causes, correct?

5 A No.

6 Q You didn't rule out any other cause or  
7 potential causes?

8 A I didn't rule out any other causes.

9 Q And you didn't investigate the rates of  
10 dyspareunia or pain in the general background  
11 and compare them to these cohorts?

12 A I did not.

13 Q And in Clave, it's fair to state that one  
14 cannot say that the complications did not  
15 occur before the degradation; is that right?

16 A It's not clear from Clave the timing of those  
17 events. My opinion is that these changes in  
18 the mesh led to those events. The mesh  
19 changed and there was an adverse event.

20 Q And the adverse events are also you mention  
21 on items number eight and nine, extrusions,  
22 inflammation, pain, and you mention erosions  
23 on nine, correct?

24 A Yes.

25 Q You didn't not do any differential diagnoses



1 on those, correct?

2 A No.

3 Q You didn't assess causation by ruling in or  
4 ruling out different causes, correct?

5 A No, I didn't do that.

6 Q In the testing that Dr. Kammerer did we  
7 talked about earlier, where in the first  
8 5 percent of elongation of the mesh, the  
9 mechanical-cut and the laser-cut were  
10 similar, do you dispute that finding?

11 A I don't dispute the finding that of the very  
12 low elongation. They are similar but --

13 Q Okay. That's my question.

14 A Yeah. Okay.

15 Q Did you look at the clinical expert report  
16 that was done by two medical doctors at  
17 Ethicon with regard to the laser-cut mesh and  
18 elongation?

19 A I think I reviewed that document, but I can't  
20 remember what it said right now.

21 Q Did that document affect your opinions?

22 A I would have to look at it again to see what  
23 it says. I don't remember.

24 Q Did you consider whether either of those  
25 doctors had any experience implanting slings

1 STATE OF KENTUCKY )  
2 )  
3 COUNTY OF DAVIESS )

4

5 I, MICHELLE E. KERR, A NOTARY PUBLIC AT LARGE IN  
6 AND FOR THE COMMONWEALTH OF KENTUCKY, DO HEREBY  
7 CERTIFY:

8 THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY  
9 AND ELECTRONICALLY BY ME AND THAT THE TYPEWRITTEN  
10 TRANSCRIPT ABOVE IS A TRUE RECORD OF THE  
11 TESTIMONY GIVEN; THAT I ALSO RECORDED AND  
12 TRANSCRIBED ANY AND ALL OBJECTIONS MADE BY COUNSEL  
13 AND THE REASONS THEREFORE; AND THAT I AM NOT A  
14 RELATIVE OR EMPLOYEE OR ATTORNEY OR COUNSEL OF ANY  
15 OF THE PARTIES, NOR A RELATIVE OR EMPLOYEE OF SUCH  
16 ATTORNEY OR COUNSEL, NOR AM I FINANCIALLY INTERESTED  
17 IN THIS ACTION.

18

19

20 IN WITNESS WHEREOF, I HAVE HEREUNTO SET MY HAND  
21 AND AFFIXED MY NOTARIAL SEAL ON THIS \_\_\_\_\_ DAY OF  
22 DECEMBER, 2014.

23

\_\_\_\_\_  
MICHELLE E. KERR, NOTARY PUBLIC

24

25 My Commission Expires:

March 21, 2017

March 21, 2017